

**REMARKS**

Claims 65 and 66 have been amended, and claim 64 has been cancelled. Care has been taken to avoid the introduction of new matter. Claims 1-3, 5, 9-33, 36-38, 41-44, 60-63, 65 and 66 are pending in the application, with claims 1, 60, 63 and 65 being independent and claims 16-32, 65 and 66 being withdrawn.

Regarding the Election/Restriction section of the Final Office Action and the withdrawal of claims 65 and 66 from consideration, these claims are amended herein to highlight even more the suitability of their inclusion for examination within the present patent application. In particular, independent claim 65 as amended clarifies that the invention is directed to a block copolymer comprising a population of molecules joined to a surface, and claim 66 likewise emphasizes the subject matter of a block copolymer as set forth in claims 65. Since the subject matter of the elected invention is a block copolymer, reconsideration of the withdrawal of these two claims, and their inclusion for examination, is respectfully requested.

Claims 1-3, 5, 11, 14, 15 and 33 were again rejected as allegedly being anticipated pursuant to 35 USC §102(e) by Hirosue et al. (US 6,254,890). Applicants respectfully traverse this rejection for the following reasons.

A patent claim is not anticipated under 35 USC §102 unless a single prior art reference discloses each and every limitation of the claim in such a way as to enable a person of skill in the art to make and use the invention without undue experimentation. *See e.g., In re Paulsen*, 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir 1994). Specifically, 35 USC §102(e) is a codification of Justice Holmes' opinion in *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926) (hereinafter *Milburn*), in which the United States Supreme Court held that a patent issued to the senior party after (but filed before) the filing date of the junior party's application may constitute prior art against the application because, having given a "complete and adequate description" of the junior party's invention, the senior party "had done all that he could to make

his description public. He had taken steps that would make it public as soon as the Patent Office did its work. . . .” *Milburn*, 270 U.S. at 399 (emphasis added). Even after the enactment of 35 USC §102(e), Justice Holmes’ opinion in *Milburn* has continued to define how an earlier filed, later published patent can constitute prior art under this section.

Thus, in *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981) (hereinafter *Wertheim*) the Court of Customs and Patent Appeals held that “if a patent [on the accused invention] could not theoretically have issued the day the [senior party’s] application was filed, it is not entitled to be used against another . . . .” *Id.* at 564 (emphasis in original). Therefore, “the determinative question is whether the invention claimed in the senior party’s publication finds a supporting disclosure in compliance with §112” and “[w]ithout such support, the invention, and its accompanying disclosure, cannot be regard[ed] as prior art....” *Id.* (emphasis in original).

The instant Final Office Action references the figure on page 8 of the September 4, 2008 Office Action, drawn by the Examiner, to illustrate what it alleges that Hirosue et al. discloses in Example 4 of the ‘890 patent. However, Example 4 states in full:

Method for Attaching Surface-Masking and/or Targeting Moieties

Surface masking characteristics are provided by PEG on the nanospheres by using various PEG-PLA and PLGA mixtures in the initial polymer solution. Non-covalent attachment of targeting moieties is achieved by incubating biotin-PEG-PLA: PLGA nanospheres with excess streptavidin or avidin, in turn, incubating the avidinylated spheres with biotin-ligand. Covalent attachment methods use activated esters (N-hydroxysuccinimidyl esters) on PEG-PLA with which amine groups from desirable ligands can be reacted.

Since the presently claimed block copolymers are, by definition, covalently bonded molecules, logically the Office Action must be relying on the last sentence of Example 4 for this rejection.

However, this language (i.e., “[c]ovalent attachment methods use activated esters (N-hydroxysuccinimidyl esters) on PEG-PLA with which amine groups from desirable ligands can be reacted”) gives absolutely no written description or enablement of the specific invention of e.g., claim 1. Neither does Hirosue et al. provide sufficient support as required by Section 112 to meet Justice Holmes’ requirement that Hirosue et al. have “done all he [they] could do” to disclose the presently claimed invention.

Respectfully, the quoted sentence does not even provide enablement or written-description support for the chemical structure presented on page 8 of the September 4th Office Action. First, Hirosue et al., while using the term “PEG-PLA,” does not provide an unambiguous definition of the chemical structure intended by this term. Secondly, the Examiner’s chemical structure on page 8 postulates that the amine moiety is linked to the PEG portion of the PEG-PLA. Hirosue, however, does not disclose this molecular arrangement. Additionally, it is not clear how this entity is attached to the nanosphere, whether the entity has a branched or linear structure, what the stoichiometry of the PEG and PLA moieties are, the molecular weight of the structure, whether there is a single or are multiple attachment points for each PEG-PLA unit to the surface, and so forth. Under the guidance of *Milburn*, in order for anticipation to be present a §102(e) reference must contain a complete and adequate description of the invention it purports to disclose; thus, the disclosure of Hirosue et al. is clearly inadequate for this purpose. Therefore, Applicants respectfully submit that Hirosue et al. is not prior art to the present claims, and that claims 1-3, 5, 11, 14, 15 and 33 are not anticipated by Hirosue et al. For these reasons, Applicants respectfully request reconsideration and withdrawal of the outstanding anticipatory rejection of the claims.

Similarly, claims 1-3, 5, 9-15, 33, 36-38 and 41-44 were rejected under 35 USC §103(a) as allegedly obvious at the time of the invention in view of Hirosue et al. and Domb et al. Applicants respectfully traverse this rejection for the reasons provided above, and the additional reasons set forth below.

Hirosue et al. is respectfully submitted not to be prior art to instant claims 1-3, 5, 9-15, 33, 36-38 and 41-44 pursuant to, e.g., *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926), and *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981). Applicants note that *Wertheim* concerned a §102(e)/103 obviousness rejection in which the priority date of the reference used by the USPTO as §102(e)/103 prior art was at issue. The *Wertheim* court held that, with regard to the subject matter used against the disclosure, “if a patent could not theoretically have issued the day the application was filed, it [the application] is not entitled to be used against another . . .” *Wertheim*, 209 U.S.P.Q. at 564 (emphasis in original). A patent cannot issue on an invention that lacks an enabling disclosure and an adequate written description. For the reasons given above, Example 4 of Hirosue et al. does not constitute an enabling disclosure or an adequate written description of an invention. Therefore, Hirosue et al. is not prior art against the present claims, either alone or in combination with Domb et al. Regarding Domb et al., the reference is cited (cf. page 9 of September 4<sup>th</sup> Office Action) solely for its alleged provision of molecular weights of PEG-PLA polymers. Thus, Domb et al., taken alone (since Hirosue et al. is not prior art), does not render the presently pending claims obvious.

For the reasons presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC §102 and §103.

In view of the above, the Examiner is requested to consider the application now to be in condition for allowance, and an early indication of same is requested. The Examiner is invited to contact the undersigned with any questions.

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The Commissioner is hereby authorized to charge any needed fees to Deposit Account 50-1600.

Respectfully submitted,



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